

# **CLIA BITS**



North Dakota Department of Health Division of Health Facilities

**Summer 2000** 

# Withdrawal of Proposed Rule

On March 17, 2000, the notice entitled "CLIA Program; Cytology Proficiency Testing," HCFA-2233-N, was published in the Federal Register. This notice announced the withdrawal of a proposed rule on cytology proficiency testing that was published in the Federal Register on Nov. 30, 1995. The 1995 proposed rule was published to comply with a court order to revise the regulations to require cytology proficiency testing be conducted "to the extent practicable, under normal working conditions." The court interpreted this to mean at a pace corresponding to the maximum workload rate for individuals examining cytology slides. The March 2000 notice withdrew the proposed rule and also contained a supplementary statement of rationale, in accordance with the appeals court ruling.



### Caution

The North Dakota Department of Health has been notified of the potential flammable danger of alcohol foam handwash used in facilities. An experiment was conducted using a common brand of alcohol foam handwash, which resulted in the foam burning. The product contained no warning about it being flammable.

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CLIA regulation 493.51 requires a laboratory issued a certificate to notify the CLIA state agency within **30 days** of a change in:

- Ownership
- Name
- Location
- Director
- Technical supervisor

The laboratory must notify the state agency within **six months** of a change in testing, including test additions, deletions and changes in test methodologies.

**All** notifications should be in writing.



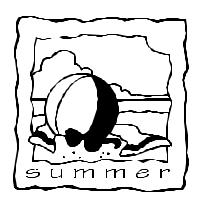
## F.Y.I.

CLIA regulation 493.801 requires certified laboratories to notify the state agency of the approved proficiency testing program or programs in which it chooses to participate to meet proficiency testing requirements. The laboratory must - for each specialty, subspecialty and analyte - participate in one approved proficiency testing program or programs for one year before designating a different program. In addition, the laboratory must notify the state agency before any change in designation and must authorize the proficiency testing program to release to the state agency all data required to determine the laboratory's compliance. Finally, the laboratory also must make proficiency testing results available to the public as required in section 353 (f) (3) (F) of the Public Health Services Act.

#### Total Laboratories Registered Nationwide Under CLIA

Certificate of Waiver	86,434 (52%)
Certificate of PPMP	35,820 (22%)
Certificate of Compliance	25,821 (16%)
Certificate of Accreditation	17,100 (10%)

#### Have a Safe & Happy Summer!



#### "ATTITUDE"

by Charles Swindoll

The longer I live, the more I realize the impact of attitude on life. Attitude, to me, is more important than facts. It is more important than the past, than education, than money, than circumstances, than failures, than successes, than what other people think or say or do. It is more important than appearance, giftedness or skill. It will make or break a company...a church...a home. The remarkable thing is we have a choice every day regarding the attitude we will embrace for that day. We cannot change the inevitable. The only thing we can do is play on the one string we have, and that is our attitude. I am convinced that life is 10% what happens to me and 90% how I react to it. And so it is with you...we are in charge of our attitudes.

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